

REMARKS

Reconsideration of the present application is requested in view of the foregoing amendments and following remarks.

I. Status of the Claims

Claims 1-7, 91, 118-120, 125, 134, 135, 147, 148, 155-158, 165, and 166 are pending in the application.

Claims 8-90, 92-117, 121-124, 126-133, 136-146, 149-154, and 159-164 have been placed in withdrawn status.

Claims 1, 2, 6, 7, 118, 134, 135, 147, and 157 have been amended to depend from claim 3.

Claim 3 has been rewritten to include a reference SEQ ID NO, and the amino acid sequence identity language has been changed from 35% to 70%. Support for the amendments can be found, *e.g.*, at page 4, lines 6-8 of the application.

Claims 91 and 125 have been rewritten in independent form.

New claims 167 and 168 have been added. These claims are similar in scope to claim 3, from which they depend, but recite higher amino acid sequence identity values. Support for the amino acid sequence identity values can be found, *e.g.*, at page 4, lines 6-8 of the application.

No new matter has been added by these amendments.

II. Restriction Requirement

Contrary to the Examiner's assertions, Applicants submit that all the claims do share a common technical feature, in which case all the claims should be examined together. The asserted finality of the Restriction Requirement should not preclude rejoinder of the non-elected claims at a future time.

III. Claim Objections

Claims 91 and 125 were objected to for depending from non-elected claims. Claims 91 and 125 have been rewritten in independent form.

Withdrawal of the objection is requested.

IV. Rejections under 35 U.S.C. § 112, second paragraph (indefiniteness)

Claim 3 and its dependents were rejected as allegedly being indefinite with respect to the reference sequence from which amino acid sequence identity can be calculated.

Claim 3 has been amended to include a reference SEQ ID NO, thereby obviating the rejection.

V. Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claims 1-3, 5-7, 118, 134, 135, 147, 148, 155-158, 165, and 166 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The rejection is traversed in view of the foregoing amendments and following remarks.

Claim 3, as amended, and from which the other rejected claims depend, is drawn to an isolated perhydrolase, wherein said perhydrolase is at least 70% homologous to *M. smegmatis* perhydrolase (SEQ ID NO: 2).

In support of such claim language, Applicants have identified, cloned, expressed, and tested the activity of the *M. smegmatis* perhydrolase enzyme (*e.g.*, pp. 163-196), determined its three-dimensional structure using enzyme crystallographic methods (*e.g.*, pp. 407-447), mutated 190 of the 216 amino acid residues in the enzyme (*i.e.*, ~88% of the residues in the polypeptide) and tested the resulting variants for activity (*e.g.*, pp. 197-371), identified, expressed, and characterized a number of homologs within 35% amino acid sequence identity (*e.g.*, pp. 372-407), and identified amino acid sequence

motif characteristic of the *M. smegmatis* perhydrolase enzyme and its homologs (*e.g.*, pp. 400-405).

Accordingly, Applicants' have characterized the *M. smegmatis* perhydrolase in a comprehensive manner, have a very clear idea of what amino acids can be changed and which should not be changed, and have described and tested a number of *M. smegmatis* perhydrolase homologs. In view of the present disclosure, the skilled person would have no doubt that Applicants were in possession of the full scope of the claimed invention at the time of filing.

New claims 167 and 168 have been added, and require the perhydrolase to be at least 80% homologous, and least 90% homologous, respectively, to *M. smegmatis* perhydrolase (SEQ ID NO: 2). For the same reasons, these claims are also fully supported by the application.

For at least the reasons discussed, above, withdrawal of the rejection is hereby requested.

VI. Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 1-3, 5-7, 118, 134, 135, 147, 148, 155-158, 165, and 166 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being supported by an enabling disclosure.

The rejection is traversed in view of the foregoing amendments and following remarks.

Claim 3, as amended, and from which the other rejected claims depend, is drawn to an isolated perhydrolase, wherein said perhydrolase is at least 70% homologous to *M. smegmatis* perhydrolase (SEQ ID NO: 2).

As described, above, in the context of written description, Applicants have identified, cloned, expressed, and tested the activity of the *M. smegmatis* perhydrolase enzyme (*e.g.*, pp. 163-196), determined its three-dimensional structure using enzyme crystallographic methods (*e.g.*, pp. 407-447), mutated 190 of the 216 amino acid residues in the enzyme (*i.e.*, ~88% of the residues) and tested the resulting variants for

activity (*e.g.*, pp. 197-371), identified, expressed, and characterized a number of homologs within 35% identity of the *M. smegmatis* perhydrolase enzyme (*e.g.*, pp. 372-407), and identified amino acid sequence motif characteristic of the *M. smegmatis* perhydrolase enzyme and its homologs (*e.g.*, pp. 400-405). Applicants have also provided detailed assays and procedures for testing variants and homologs (*e.g.*, pp. 146-158).

In view of what is disclosed in the specification, combined with what is known in the art, the skilled person would have no difficulty in identifying and testing all polypeptides encompassed by the full scope of the claims, as amended, and without undue experimentation.

New claims 167 and 168 have been added, and require the perhydrolase to be at least 80% homologous, and least 90% homologous, respectively, to *M. smegmatis* perhydrolase (SEQ ID NO: 2). For the same reasons, these claims are also fully supported by the application.

For at least the reasons discussed, above, withdrawal of the rejection is hereby requested.

VII. Rejections under 35 U.S.C. § 102

Claims 1, 2, 118, 134, 135, 147, 148, 157, and 158 were rejected under 35 U.S.C. § 102 as allegedly anticipated by Poulouse *et al.* (USPN 5,108,457).

The rejection is traversed in view of the foregoing amendments and following remarks.

A. The pending claims

The pending claims, as exemplified by claim 3 (as amended) are drawn to an isolated perhydrolase, wherein said perhydrolase is at least 70% homologous to *M. smegmatis* perhydrolase (SEQ ID NO: 2).

B. The cited art

Poulose *et al.* (USPN 5,108,457) describe modified lipase enzymes having improved ratios of peracid/acid formation (col. 10, lines 4-18).

C. Analysis

The rejection is traversed because Poulose *et al.* do not describe the claimed invention. As shown, below, the amino acid sequence described in Poulose *et al.* (as recited in claim 1 of USPN 5,108,457)¹ shares less than 14% amino acid sequence identity to SEQ ID NO: 2.

Total alignment length: 258
Number of identity: 29
Number of residues aligned: 216
BLAST style alignment length: 232
Percent identity (BLAST style): 12.50%
Percent identity (GAP style): 13.43%
Percent identity (Needle style): 11.24%

CLUSTAL W (1.83) multiple sequence alignment

```
30821_SEQIDNO_2      -----MAKRILCFGDSLWTGWVPEVDGAPTER-----FAPDVRWTG
EP037510281          APLPDTFGAPFTTSAVARIYNFDITWQLPPGDDQVSFGYTSAGFQSQQEGGGFRPDAGVSD
                        :. : : : ** * : * ..                * *. :.

30821_SEQIDNO_2      VLAQQLGADFEVIEEGLSARTTN---IDDPDTPRLNGASYLPSC LATHLPDLVIIMLGT
EP037510281          AWYGPGLRFRWGMGVGYALRGNTHLG SNGTPRLYL RGRGHPICSSSDREGYTFQLQTL
                        .   * * : * : * * :.. *** . . : : . . : :

30821_SEQIDNO_2      NDTKAYFRRTPLDIALGMSVLVTQVLT SAGGVGTTYPAPKVLVVSPPPLAPMPHPWFQLI
EP037510281          TYSSVATAYMTIANQFSSNPDVDEWLPVGPYTPAQRQALAGMLNASHHASQSRFRIFFFRS
                        . :.. . : . . : : . . . . : * . * . . * : : *

30821_SEQIDNO_2      FEGGEQKTTELARVYSALASFMKVPFFDAGSVISTDGVDGIHFTEANNRDLGVALAEQVR
EP037510281          GRRGEEKCHGSARMWDGPAALRARSGTRRLAVIPGAMY EADHSSVSLGGVG GTYITITGV
                        . ** : * ** : .. ** : . : ** . :. * : : . * .

30821_SEQIDNO_2      SLL-----
EP037510281          QGVCTLN GYGVP CGRRGL
                        . :
```

For at least these reasons, it is apparent that Poulose *et al.* do not anticipate the claimed invention. Withdrawal of the rejection is requested.

¹ In the absence of a Sequence Listing, Applicants used Adobe® Optical Character Recognition (OCR) to obtain an electronic sequence for use in the Clustal W alignment. Applicants subsequently attempted to correct OCR errors. Any remaining errors are unintentional and without deceptive intent.

VIII. Rejections under 35 U.S.C. § 103

Claims 3 was rejected under 35 U.S.C. § 102 as allegedly obvious over Poulouse *et al.* (USPN 5,108,457) in view of UniProt Accession No. Q92XZ6.

The rejection is traversed in view of the foregoing amendments and following remarks.

A. The pending claims

Claim 3, as amended, is drawn to an isolated perhydrolase, wherein said perhydrolase is at least 70% homologous to *M. smegmatis* perhydrolase (SEQ ID NO: 2).

B. The cited art

Poulouse *et al.* (USPN 5,108,457) describe modified lipase enzymes having improved ratios of peracid/acid formation (col. 10, lines 4-18).

UniProt Accession No. Q92XZ6 is a putative hydrolase having an earliest possible publication date of December 1, 2001.²

C. Analysis

Poulouse *et al.* are discussed above. It should be apparent that Poulouse *et al.* neither teach nor suggest an enzyme that meets the requirement of claim 3 or its dependents. UniProt Accession No. Q92XZ6 is an annotated amino acid sequence sharing only about 63-64% amino acid sequence identity to SEQ ID NO: 2.

Total alignment length: 218
Number of identity: 138
Number of residues aligned: 216
BLAST style alignment length: 216
Percent identity (BLAST style): 63.89%
Percent identity (GAP style): 63.89%
Percent identity (Needle style): 63.30%

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CLUSTAL W (1.83) multiple sequence alignment

```
Q92XZ6          MVEKRSVLCFGDSLWTGWIPVKESPTLRYPEQRWTGAMAARLGDGYHIEEGLSARTT
30821_SEQIDNO_2  --MAKRILCFGDSLWTGWVPVEDGAPTERFAPDVRWTGVLAQQLGADFEVIEEGLSARTT
                  : :*****:***::** *:. : ****.:* :** .::*****
```

² Applicants have not determined whether the UniProt entry is entitled to the earliest possible priority and reserve the right to raise this issue in a future Office Action Response.

Q92XZ6 SLDDPNDARLNGSTYLPALASHLPLDLVIIMLGTNDTKSYFHRTPYEITANGMGLKVGQV
30821_SEQIDNO_2 NDDPTDPTDLNGASYLPSCLATHPLDLVIIMLGTNDTKAYFRRTPLDIALGMSVLVTQV
.:***.*.***.:***.**:*****:***:***.***.***.***

Q92XZ6 LTCAGGVGTYPYAPKVLVVPFPLAPMPDPWFEGMFGGGYEKSKELSGLYKALADFMKVE
30821_SEQIDNO_2 LTSAGGVGTTPYAPKVLVVPFPLAPMPHPWFQLIFEGEQKTELARVYSALASFMKVP
.**.****:*****:***:***:***:***.***.***

Q92XZ6 FFAAGDCISTDGIDIGIHLSAETNIRLGHAIADKVAALF
30821_SEQIDNO_2 FFDAGSVISTDGVGDGHFTEANNRDLGVALAEQVRSL
.**.****:***:***:***:***:***:***

Since neither the polypeptide described in Poulou et al., nor the polypeptide corresponding to UniProt Accession No. Q92XZ6 meet the requirements of claim 3, as amended, neither reference, alone or in combination, anticipate or render obvious the claimed invention.³

Withdrawal of the rejection is respectfully requested.

IX. Conclusion

If the Examiner has any questions or believes that a telephone conversation would expedite examination, he is encouraged to contact the undersigned. The USPTO is authorized to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. **07-1048**.

Respectfully submitted,

Date: May 26, 2011

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³ Applicants in no way concede that the polypeptide corresponding to UniProt Accession No. Q92XZ6 is a perhydrolase, and reserve the right to argue this point in a future Office Action Response.